NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DUSA PHARMACEUTICALS, INC., and SIRIUS LABORATORIES, INC., a wholly-owned subsidiary of DUSA PHARMACEUTICALS, INC., Plaintiffs, v. RIVER'S EDGE PHARMACEUTICALS, LLC, Defendant.	**Hon. Stanley R. Chesler, U.S.D.J.** **Civ. No. 06-1843 (SRC)** **OPINION**

CHESLER, District Judge

THIS MATTER comes before the Court on the Motion of Plaintiffs DUSA Pharmaceuticals, Inc. ("DUSA") and Sirius Laboratories, Inc. ("Sirius II") (jointly "DUSA") for a Preliminary Injunction pursuant to Federal Rule of Civil Procedure 65(a) enjoining Defendant, River's Edge, from infringement of the claims of DUSA's U.S. Patent No. 6,979,468 (the '468 patent"). For the reasons set forth below, this Court will **GRANT** Plaintiffs' Motion.

I. BACKGROUND

This action arises out of Defendant River's Edge's alleged infringement of the '468

patent held by DUSA. . DUSA is a publicly traded pharmaceutical company incorporated in the State of New Jersey with its principal place of business in Massachusetts. (Compl. ¶ 5.) On April 21, 2006, Plaintiffs filed the Complaint in this matter alleging Defendant is infringing on one or more claims of DUSA's '468 patent. Simultaneously, Plaintiffs filed the instant Motion for a Preliminary Injunction enjoining River's Edge from continued infringement.

On December 27, 2005, the '468 patent, entitled "Oral Composition and Method for the Treatment of Inflammatory Cutaneous Disorders" was issued to the inventor, Frank Pollard. The '468 patent is directed to an oral pharmaceutical preparation for the treatment of inflammatory skin disorders such as acne vulgaris and rosacea. The composition claims in the '468 patent comprises of nicotinamide in an immediate release form, and zinc in a sustained release form. Initially, the '468 patent was assigned to Sirius Laboratories, Inc., ("Sirius I"). (Compl. ¶¶ 8-9.)

Sirius I previously marketed and sold a prescription-only oral pharmaceutical product for the treatment of inflammatory skin disorders under the trademark Nicomide® having immediate release forms of both nicotinamide and zinc. In 2003, while the application of the '468 patent was pending, Sirius I released a new formulation of Nicomide® having an immediate release nicotinamide and a sustained release zinc as described in the '468 patent. (Pl. Ex. D, ¶ 9.) The reformulation of Nicomide® provided tangible benefits and avoided many of the negative side effects associated with other treatments. Nicomide® proved to be a successful oral treatment for inflammatory skin disorders and generated net revenues of approximately $7.3 million in 2005. (Pl. Ex. D at ¶¶ 18-20; Pl. Ex. E at ¶ 12.)

On or about March 10, 2006, in light of the success of Nicomide®, DUSA acquired Sirius I by a merger, thus dissolving Sirius I and establishing a DUSA wholly-owned subsidiary

named Sirius Laboraties, Inc. ("Sirius II"). The '468 patent has been assigned to DUSA and duly recorded with the United States Patent and Trademark Office. (Pl. Ex. A.1.) The reformulated Nicomide® product is currently marked and sold by DUSA.

On or about March 17, 2006, DUSA and Sirius II, received a letter from Steven J. Hultquist of Intellectual Property Technology Law on behalf of an anonymous client. (Pl. Ex. F-1.) The March 17 letter purported to identify prior art that, Mr. Hultquist claimed, rendered the '468 patent invalid, and requested that DUSA and Sirius II file a dedication to the public and disclaimer of the remaining term of the '468 patent. (Id.) Counsel for DUSA and Sirius II responded by letter on or about March 23, 2006 requesting that Mr. Hultquist provide a basis for questioning the validity of the '468 patent, and requested to communicate with Mr. Hultquist's client regarding the unidentified client's "activities or intended activities, and a potential business resolution." (Pl. Ex. F-2.) DUSA received no response to this letter.

On or about March 28, 2006, Defendant River's Edge filed a lawsuit against DUSA and Sirius II in the United States District Court for the Northen District of Georgia, asserting claims of promissory estoppel and fraud, and seeking a declaratory judgment of patent invalidity. (Id. ¶ 2, Pl. Ex. F.) In the Georgia complaint, River's Edge stated that it began marking its product, NIC 750, on or about March 27, 2006. (Pl. Ex. F. at 7.) River's Edge has listed its NIC 750 in the National Drug Data File® ("NDDF"), a source consulted by physicians, pharmacists, hospitals, and clinicians to identify potential substitute equivalents of branded pharmaceuticals. (Pl. Ex. C-1.) NIC 750 is listed in the NDDF as an equivalent substitute for DUSA's prescription Nicomide® product. (Id.)

On or about April 21, 2006, DUSA filed the Complaint in this matter alleging patent

infringement and seeking monetary damages and injunctive relief. Contemporaneously, DUSA filed the instant motion for a preliminary injunction. On May 1, 2006, River's Edge filed a Request for *Inter Partes* Reexamination of the '468 patent with the U.S. Patent and Trademark Office[1]. The Court held oral argument on May 5, 2006.

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[1]On or about May 1, 2006, River's Edge also filed a separate motion to stay, dismiss or transfer this civil action (docket entry # 14). River's Edge argues, in part, that venue is improper in this district because it is a Limited Liability Company ("LLC"), and does not meet the venue requirements of 28 U.S.C. § 1400(b). (Def. Brief To Stay, Transfer or Dismiss 7.)

Venue in patent infringement actions, like the case at bar, is governed by 28 U.S.C. § 1400(b) which permits an infringement action to be brought in the judicial district where, (1) the defendant resides, or (2) where substantial acts of infringement occur and where the defendant has a regular and established place of business. 28 U.S.C. § 1400(b). Pursuant to the 1988 amendments to 28 U.S.C. § 1391(c), a corporation is "deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." This amendment to the general venue statute has been held to apply to section 1400(b). See VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1580 ("Section 1391(c) applies to all of chapter 87 of title 28, and thus to § 1400(b)").

Defendant argues that § 1391(c) applies to § 1400(b) only when the defendant is a corporation, and not when the defendant is an unincorporated association, like an LLC. To support this proposition Defendant relies on a footnote from VE Holding which addressed the notion that incorporating § 1391(c) would render § 1400(b)'s second test meaningless. The court dismissed this argument stating "§ 1400(b) applies to all defendants, not just corporate defendants, and thus the second test for venue remains operative with respect to defendants that are not corporations." 917 F.2d at 1580 n.17. This statement, however, is *obiter dictum*. Defendant does not point to any authority recognizing this interpretation, or treating LLCs differently than corporations for purposes of venue.

The Supreme Court established in 1967 that an unincorporated business entity is treated as a corporation for venue purposes. Denver and Rio Grande Western Railroad Co. v. Brotherhood of Railroad Trainmen, 387 U.S. 556, 559-60 (1967). This holding has been followed by many federal district courts. See McCallum v. N.Y. Yankees P'ship, 392 F. Supp. 2d 259, 263 n.2 (D. Conn. 2005) (applying § 1391(c) to a partnership where three of the four partners were corporations); Injection Res. Specialists v. Polaris Indus. L.P., 759 F. Supp. 1511, 1512-16 & n.9 (D. Colo. 1991) (applying § 1391(c) to a limited partnership); Pippett v. Waterford Develop. LLC, 166 F. Supp. 2d 233, 238 (E.D. Pa. 2001) ("An unincorporated association has no citizenship independent of its members for determining jurisdiction, but for determining venue it is treated as a corporation"). Venue, therefore, is proper in any judicial district where River's Edge resides. Under § 1391(c), venue will lie wherever River's Edge is subject to personal jurisdiction. Here, River's Edge has not contested personal jurisdiction and will, therefore, be considered a resident of New Jersey for venue purposes.

II. DISCUSSION

1. Standard for a Preliminary Injunction

Pursuant to 35 U.S.C. § 283, this Court may grant an injunction to "prevent the violation of any right secured by patent." The decision to grant or deny a preliminary injunction is within the discretion of the district court. To obtain this type of relief, however, a movant must demonstrate: "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." Oakley, Inc. v. Sunglass Hut Intern'l., 316 F.3d 1331, 1338-39 (Fed. Cir. 2003); see Council of Alternative Political Parties v. Hooks, 121 F.3d 876, 879 (3d Cir. 1997).

2. DUSA's Motion for a Preliminary Injunction

A. Likelihood of Success on the Merits

To obtain preliminary injunctive relief, DUSA must show, in light of the burdens in place

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In its separate motion to dismiss, Defendant also argues that this Court should dismiss this civil action pursuant to the first-to-file rule. This Court will defer decision on Defendant's application until the Georgia district court rules on DUSA's motion to dismiss, pending before that court, and decides whether River's Edge's declaratory judgment action should be entertained. Under any circumstances, this Court would not be inclined to dismiss, even if the first-to-file rule did apply. At most, the Court would transfer this action pursuant to 28 U.S.C. § 1404(a). Therefore, the pendency of Defendant's motion is not a bar to the Court issuing the instant preliminary injunction.

Defendant also seeks a stay of the current action pending resolution by the PTO of River's Edge's Request for Re-Examination of the '468 patent. The Court is satisfied that Defendant's application for a stay should, at this point, be denied in light of the fact that Defendant's Request has not yet been granted by the USPTO. Pursuant to 35 U.S.C. § 318, a patent owner may obtain a stay of pending litigation, "[o]nce an order for inter partes reexamination has been *issued* under section 313." 35 U.S.C. § 318 (emphasis added). Therefore, this Court will deny Defendant's request for a stay as premature. See Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1424 (Fed. Cir. 1988) (acknowledging that the district court denied a request to stay litigation where the request was filed before the USPTO had granted the reexamination).

at trial, that it is likely to prove that the '498 patent is valid, that it is infringed by NIC 750, and that it will withstand River Edge's allegations of patent invalidity. See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

1. *Validity*

Once issued, every patent is entitled to a presumption of validity. 35 U.S.C. § 282. The party challenging the validity of a patent bears the burden of establishing invalidity with facts supported by clear and convincing evidence. See Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 872 (Fed. Cir. 1985); Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1088 (Fed. Cir. 1998). The presumption of validity, however, does not relieve a party moving for a preliminary injunction from its burden to demonstrate a likelihood of success on the merits of all disputed issues at trial. At the preliminary injunction stage, therefore, DUSA bears the burden "of showing a reasonable likelihood that the attack on its patent's validity would fail." Oakley, 316 F.3d at 1339; see New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 883 (Fed. Cir. 1992) ("While it is not the patentee's burden to prove validity, the patentee must show that the alleged infringer's defense lacks substantial merit").

a. Anticipation

River's Edge contends that the '468 patent is invalid because it was anticipated by prior art. (Def. Br. 5.) Under 35 U.S.C. § 102(b), an invention is anticipated if it "was . . . described in a printed publication in this . . . country . . . more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b). In other words, a prior art reference anticipates a patent claim if that single reference discloses, either expressly or inherently, all limitations of the claim. Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354, 1356 (Fed. Cir.

1999). The issue of anticipation is resolved by performing a comparison between the prior art reference and the assert claims. See Helifix Ltd. v. Block-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994). The absence from the prior art reference of any claimed element negates anticipation. See Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565, 1571 (Fed. Cir. 1986).

To prevail, River's Edge has the burden of proving there is a substantial question concerning whether the '468 patent is anticipated by a single prior art reference that disclosed each and every limitation of the claimed invention. Thus, to prevail on the instant motion for preliminary injunction, DUSA must prove that River's Edge's invalidity defense of anticipation lacks substantial merit.

River's Edge contends that the '468 patent is anticipated by eleven prior art[2] references: U.S. Patent Nos.: 5,053,396 ("Blass"); 4,740,373 ("Kesselman"); 5,308,627 ("Umbdenstock"); 5,626,884 ("Lockett"); 6,299,896 ("Cooper"); 5,759,559 ("Fitzjarrell"); 4,505,896 ("Bernstein"); 4,725,609 ("Kull"); 5,989,523 ("Fitzjarrell II"); 6,248,763 ("Scivoletto"); and WIPO Patent Application Publication No. WO 01/56572 A1 ("Bland"). (Def. Br. 8-9; Hultquist Decl., Ex. A, Request for Reexamination of the '468 patent ("Request"), at 6-8.)

The '468 patent contains fifteen claims. (Pl. Ex. A.) A comparison of the claims embodied in the '468 patent with those embodied in the eleven prior art references reveals that

[2]DUSA disputes whether the references Defendant identifies as prior art actually qualify as prior art under 35 U.S.C. § 102(b). However, for purposes of this motion only, the Court will assume that each qualify as prior art.

not one of these references contains each of the claims in the '468 patent. For example, claim 1 of the '468 patent instructs:

> An oral pharmaceutical preparation in dosage unit form adapted for administration for the treatment of inflammatory skin disorders, comprising, per dosage unit at least 250 mg nicotinamide in an immediate release form, and *an amount of zinc in a sustained release form*, said amount of zinc being sufficient to provide an enhanced anti-inflammatory effect, in a vehicle pharmaceutically acceptable for oral administration.

(Pl. Ex. A.) (emphasis added). The '468 patent states that "zinc may be present as any pharmaceutically acceptable zinc salt, zinc complex or zinc chelate." The specification goes on to state that while zinc oxide is a preferred zinc salt, "other zinc salts, such as zinc sulfate and zinc gluconate, zinc complexes and zinc chelates may be substituted, in the sustained release form for the zinc oxide." ('468 patent, 3:5-7, 8-11.) Plaintiffs contend that none of the prior art patents require zinc in a sustained release form and, therefore, cannot be said to anticipate the '468 patent.

Defendant contends that seven of the prior art references reveal known sustained release forms of zinc. (Request, at 24-25.) A review of the seven claims reveals that each patent calls for a form of zinc or zinc compound which Defendant asserts is a "known sustained release form" of zinc. (Id.) For example, the Cooper patent states, " . . . zinc is dosed in the form of a pharmaceutically acceptable zinc compound . . . acceptable zinc compounds include . . . zinc sulfate, zinc chloride, zinc oxide, and combinations thereof." (Id. at 24.) Defendant states in the "comment" column of the table that 'zinc sulfate' and 'zinc oxide' are known sustained release forms of zinc." (Id.)

Nothing in Defendant's Brief, Request, or the declaration of Hultquist provides any

evidence that the cited patents disclose the combination of nicotinamide in an immediate release form and zinc in a sustained release form – a required element of every claim of the '468 patent. The Request does not, on its face, establish anticipation. Defendant presents no evidence that the zinc forms listed in the prior art references are commonly known to be sustained release forms. The only evidence River's Edge submitted in support of its argument is the Hultquist declaration. Mr. Hultquist is a patent attorney and purports to be qualified as a patent *law* expert. (Hultquist Decl., at ¶ 7.) This declaration does not establish that one of ordinary skill in the art would interpret the prior art to contain zinc in a sustained release form.

DUSA contends that various active ingredients can be formulated in varying ways, including to be a "sustained release form" or "immediate release form." (Pl. Rep. Br. 10.) To support this conclusion, Plaintiffs present the declaration of Robert O. Williams, III ("Williams"), as one skilled in the art[3]. Williams submits that a person of ordinary skill in the art would know that the zincs listed in the prior patents are not known as sustained release forms. (Williams Decl., Ex. C, ¶ 16.) Additionally, Williams opines that none of the prior art references disclose zinc in a sustained release form in combination with nicotinamide in an immediate release form, as required by claim 1 of the '468 patent. (Id. at ¶ 15.)

DUSA also relies on the prosecution history of the '468 patent to reinforce the distinction between "sustained release" as a dosage form, and a zinc salt, complex or chelate itself

[3]Williams received a B.S. in biology from Texas A&M University in 1979, a B.S. in pharmacy from the University of Texas at Austin in 1981, and a PhD in pharmaceutics from the University of Texas at Austin in 1986. He has extensive experience in pharmaceutical formulation and the use of excipients in formulating immediate release and sustained release drug dosage forms and has many years experience working in the pharmaceutical industry. (Williams Decl., Ex. C, ¶¶ 3-5.)

constituting a sustained release form. During prosecution, the PTO Examiner initially asserted that because zinc oxide "lacked sufficient solubility in physiological system [sic]" it would, by virtue of this insolubility, not be immediate release (*i.e.*, it would be in the "sustained release form"). (Ex. C-1, Office Action, December 2, 2004, p.3.) However, the Examiner subsequently abandoned this argument and allowed the claims to issue in their present form. Plaintiffs assert that this history demonstrates two points: (1) the PTO understood the clear distinction made in the patent between zinc in a "sustained release form" and the zinc salt, complex or chelate generally; and (2) that the solubility of zinc oxide – or any other zinc salt, complex or chelate – did not render the zinc a "sustained release form" as that term is commonly understood by one of skill in the art. (Pl. Reply Br. 11-12.) The record before this Court does not demonstrate that every claim limitation of the '468 patent is contained in a single prior art reference and, therefore, does not raise a substantial question that the '468 patent is invalid as anticipated.

b. Obviousness

River's Edge also attacks the validity of the '468 patent by claiming that the invention was obvious in light of relevant prior art. Pursuant to 35 U.S.C. § 103, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). When evaluating the obviousness or non-obviousness of a patent claim, courts look to the totality of the evidence, including: (1) the scope and content of the prior art; (2) the differences between the art and the claims at issue; (3) the level of ordinary skill in the art; and, (4) critical objective evidence of non-obviousness, such as commercial success, failure of others,

copying and unexpected results. See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983); Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). "Objective considerations such as failure by others to solve the problem and copying 'may often be the most probative and cogent evidence' of nonobviousness." Advanced Display Systems, Inc. v. Kent State University, 212 F.3d 1272, 1285 (quoting Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983).

To support a finding of non-obviousness, DUSA relies on several items of objective evidence. First, DUSA contends that the commercial success of Nicomide® weighs in favor of the invention being non-obvious. In 2005, Nicomide® sales totaled approximately $7.3 million. (Pl. Ex. E at ¶ 12.) Second, DUSA points to a recent publication describing an 8-week, open label study[4] evaluating the effectiveness of the invention of the '468 patent. (Pl. Br. 20.) This publication praised Nicomide® as providing unique advantages in treatment by avoiding many of the risks and side-effects associated with existing established forms of treatment for acne. Plaintiffs' assert that this study is persuasive evidence of industry recognition and acclaim. Lastly, Plaintiffs point to Defendant's own conduct in establishing non-obviousness. As acknowledged in the Georgia complaint, River's Edge approached Sirius I seeking a business arrangement whereby River's Edge would be permitted to "market a low-cost product containing the same active ingredients as NICOMIDE, on a profit sharing basis." (Pl. Ex. F at 4.) Plaintiffs argue that by seeking an authorized avenue to exploit the value of the invention, River's Edge's conduct must be considered a recognition of the value and non-obviousness of the '468 patent.

[4]The study is referred to as the "Nicomide® Improvement in Clinical Outcomes Study" ("NICOS") and was recently published in *Cutaneous Medicine for the Practitioner*, a supplement to the journal *Cutis*.

(Pl. Br. 22.)

River's Edge does not challenge or refute any of the objective considerations presented by DUSA. Rather, in opposition, Defendant contends that because it was known, at the time of Pollard's invention, to use immediate release nicotinamide for treating acne and to use zinc for treating acne, it would have been obvious to one of ordinary skill in the art to combine the two into a single formulation for the treatment of acne, as recited in claims 1-9 and in method claim 16 of the '468 patent. (Def. Br. 8.) Likewise, River's Edge asserts that it was previously known to provide copper supplementation with zinc and, therefore, it would have been obvious to one of ordinary skill in the art to combine copper with the nicotinamide and zinc formulation for the treatment of acne, as recited in claims 10-15 of the '468 patent. (Id.) In support of its argument, Defendant relies on the information contained in its Request for reexamination and concludes that a review of the Request "demonstrates that all claims . . . of the '468 patent are invalid as being . . . obvious . . . in view of the disclosures of one or more of the prior art references described" in the tables in Defendant's Request. (Def. Br. 9.) Defendant does not, however, address how the scope and content of the prior art bears on the specific elements of the '468 claims. Similarly, River's Edge does not demonstrate, or provide the affidavit of an expert to demonstrate, how any claims or teachings from the prior art make obvious the combination of zinc in a "sustained release form" with nicotinamide in an immediate release form, as required by every claim of the '468 patent. The Court, therefore, finds that DUSA has met its burden by demonstrating a "reasonable likelihood that the attack on its patent's validity would fail."

Oakley, 316 F.3d at 1339.[5]

2. *Infringement*

In order to obtain a preliminary injunction, DUSA must further show that it is likely to prove infringement by River's Edge. As the patent holder, DUSA bears the burden of proving infringement. See Under Sea Indus., Inc. v. Dacor Corp., 833 F.2d 1551, 1557 (Fed. Cir. 1987). Infringement analyses are traditionally performed in a two-step process. First, the patent claims are construed to ascertain their proper scope. See N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1574 (Fed. Cir. 1994); Seal-Flex, Inc. v. Athletic Track and Court Construction, 172 F.3d 836, 842 (Fed. Cir. 1999). Second, the construed claims are compared to the allegedly infringing products or processes to determine whether those products or processes fall within the scope of those claims literally or under the doctrine of equivalents. Id. An infringer need only infringe one claim of a patent in order to be liable. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1220 (Fed. Cir. 1995). However, to prove literal infringement, a plaintiff must show that the infringing device contains or "reads on" each and every limitation disclosed in a given patent claim. Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998).

Although claims must be construed to determine infringement, a court need not arrive at a final and conclusive claim construction in deciding a motion for preliminary injunction, see Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996), and a court's findings and conclusions regarding claim construction are not binding at trial. See

[5]The Court notes that Defendant, for the first time, raises additional arguments relating to invalidity in an unsolicited "Supplemental Memorandum" submitted to the Court after oral argument. The Court declines to consider arguments which were not properly raised in Defendant's opposition papers.

Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F. 2d 679, 681 (Fed. Cir. 1990). In short, a court's obligation at the preliminary injunction state is only to determine the probability that infringement can be proved after a full presentation of the evidence at trial. Atari Games Corp. v. Nintendo of America, Inc., 897 F.2d 1572, 1575 (Fed. Cir. 1990).

DUSA contends that River's Edge's product, NIC 750, satisfies every limitation of claim 1 of the '468 patent. (Pl. Br. 12.) Plaintiffs base this contention upon a comparison of the product packaging insert for NIC 750 against the limitations of claim 1of the '468 patent. (Id.; Pl. Ex. C.) The following chart is taken from Plaintiffs' Brief in support of their motion for a preliminary injunction and illustrates the comparison:

'468 PATENT CLAIM	**RIVER'S EDGE'S NIC 750 PRODUCT**
1. An oral pharmaceutical preparation	"NIC 750 Tablets for oral administration are white colored tables," (Pl. Ex. C-1., NIC 750 Package Insert, Description.)
in dosage unit form	"Usual adult dose is one tablet taken once or twice a day or as prescribed by a physician." (Pl. Ex. C-1.)
adapted for administration for the treatment of inflammatory skin disorders, comprising,	NIC 750 is "[i]ndicated for non-pregnant patients with acne vulgaris, acne rosacea or other inflammatory skin disorders who are deficient in, or at risk of deficiency in, one or more of the components of NIC 750." (Pl. Ex. C-1.)
per dosage unit at least 250 mg nicotinamide	"Each oral tablet provides: Nicotinamide, USP 750 mg" (Pl. Ex. C-1.)
in an immediate release form, and	"The biphasic delivery system facilitates the immediate release of 750 mg Nicotinamide," (Pl. Ex. C-1.)
an amount of zinc	"Each oral tablet provides: . . . Zinc Oxide, USP 25 mg" (Pl. Ex. C-1.)

in a sustained release form,	"The biphasic delivery system facilitates the immediate release of 750 mg Nicotinamde, . . . as well as, the sustained release of 25 mg Zinc Oxide." (Pl. Ex. C-1.)
said amount of zinc being sufficient to provide an enhanced anti-inflammatory effect,	"Zinc has been shown to inhibit the inflammatory polymorphonuclear leukocyte chemotaxis in acne patients. Zinc has also demonstrated an inhibitory effect on the lipase of the three Propionibacterium species found in human pilosebaceous follicles." (Pl. Ex. C-1.)
in a vehicle pharmaceutically acceptable for oral administration.	"NIC 750 Tablets for oral administration are white-colored tablets," (Pl. Ex. C-1.)

(Pl. Br. 12-13; Pl. Ex. C.) NIC 750 meets every claim limitation of claim 1 of the '468 patent.

River's Edge's primary defense against infringement is its argument that the '468 patent is invalid and, therefore, DUSA cannot succeed on their claim for infringement because an invalid patent cannot be infringed. (Def. Br. 5.) In light of DUSA's persuasive, uncontradicted evidence, this Court finds that DUSA has shown that it is likely to prove literal infringement on claim 1.

B. Irreparable Harm

On a motion for a preliminary injunction, a patentee that shows a likelihood of success on the merits of patent validity and infringement is entitled to a presumption of irreparable harm. See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566-67 (Fed. Cir. 1996). "Because of the very nature of a patent, which provides the right to exclude, . . . infringement of a valid patent *inherently* causes irreparable harm in the absence of" circumstances negating that harm. Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 974-75 (Fed. Cir. 1996). Here, DUSA's

refutation of each of River's Edge's validity challenges to the '468 patent and its essentially undisputed evidence of literal infringement constitute a showing of likelihood of success on the merits. Accordingly, irreparable harm to DUSA is presumed.

However, this presumption is rebuttable. The effect of the presumption is to place the burden on River's Edge "to produce evidence sufficient to establish that [DUSA] would not be irreparably harmed by an erroneous denial of its motion for preliminary injunction." Polymer Techs., 103 F.3d at 974. Generally, evidence that will rebut the presumption is: evidence that (1) the infringer has or will soon cease the allegedly infringing activities, thus making an injunction unnecessary; (2) the patentee has already granted licenses under the patent, such that is reasonable to expect that infringement of the patent cannot be remedied with a royalty rather than with an injunction; or (3) the patentee unduly delayed filing suit on the infringement, thereby negating and undermining the irreparability claim. See Polymer Techs., 103 F.3d at 974.

River's Edge has presented no evidence challenging any of these factors. The record before this Court is devoid of any evidence demonstrating that River's Edge will cease infringing the '468 patent, that DUSA has previously granted licenses under its patent, or that DUSA delayed in filing suit for patent infringement. Instead, again relying solely on its Request for reexamination, Defendant argues that DUSA is not entitled to the presumption of irreparable harm because the '468 patent is invalid in light of prior art. (Def. Br. 11-12.) Having already concluded that DUSA met its burden showing that River's Edge's attacks on the validity of the '468 patent will likely fail, the Court is unpersuaded by this argument.

To further bolster their showing of irreparable harm, DUSA has presented additional evidence demonstrating how Defendant's infringement will cause irreparable harm. DUSA

contends that the entry of River's Edge's NIC 750, being marketed as a generic substitute for Nicomide®, will cause considerable erosion of DUSA's exclusive market share. (Pl. Br. 27.) DUSA presented several reports and studies which documented the rapid and substantial decline in market share branded drugs face when generic versions enter the market. The record before this Court demonstrates that River's Edge has failed to rebut the presumption and DUSA has shown irreparable harm.

C. Balance of the Hardships

Before this Court may award DUSA a preliminary injunction against River's Edge, it must balance the hardships facing both parties from the grant or denial of injunctive relief. In doing so, "[t]he magnitude of the threatened injury to the patent owner is weighed, in light of the strength of the showing of likelihood of success on the merits, against the injury to the accused infringer if the preliminary decision is in error." H.H. Robertson Co. v. U.S. Deck, Inc., 820 F.2d 384, 390 (Fed. Cir. 1987). For DUSA, in the absence of a preliminary injunction, River's Edge will continue to infringe on its '468 patent, and continue to detract from DUSA's market share and to compete with DUSA in a market in which DUSA has the right to exclude.

River's Edge, in arguing that the balance of equities weigh in its favor, returns to its argument that the '468 patent is invalid. Defendant argues that a preliminary injunction would require River's Edge to delay bringing its "lawful product" to market. (Def. Br. 12-13.) This Court, however, has found that DUSA demonstrated a likelihood that challenges to the validity of the '468 patent would fail. Additionally, this Court has found that DUSA is likely to prove that River's Edge's product NIC 750 infringes on DUSA's '468 patent. Therefore, any hardship River's Edge suffers is a necessary and predictable consequence of its decision to market and sell

NIC 750 in light of the '468 patent. Accordingly, this Court finds that the balance of hardships tips in favor of DUSA.

D. Public Interest

Lastly, this Court must consider the impact of injunctive relief on the public interest. The public interest strongly favors protecting the rights secured by a valid patent. See Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983). River's Edge does not point to any public interest that would favor denying the injunctive relief sought here. Instead, Defendant relies on its primary argument: that the '468 patent is invalid. Defendant, therefore argues that the public interest would not be served by the enforcement of an invalid patent. (Def. Br. 13.) Again, this Court has found that DUSA demonstrated a likelihood that challenges to the validity of the '468 patent would fail. Accordingly, the Court finds the public interest in protecting valid patents weighs in favor of injunctive relief in this case.

III. CONCLUSION

DUSA has satisfied its burden by demonstrating, (1) a likelihood of success on the merits of their claim for patent infringement by River's Edge, (2) that River's Edge's attack on the validity of the '468 patent would likely fail, (3) that DUSA would suffer irreparable injury without injunctive relief, (4) the balance of hardships weigh in favor of DUSA, and (5) that the public interest favors granting DUSA's requested injunctive relief. Therefore, this Court will GRANT Plaintiffs' Motion for a Preliminary Injunction. An appropriate form of order will follow.

s/ Stanley R. Chesler

Stanley R. Chesler, U.S.D.J.